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Attorney Docket No.: 24852-501 CIP2

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

APPLICANTS: Chiao et al.  
SERIAL NUMBER: 10/616,649 EXAMINER: Not Yet Assigned  
FILING DATE: July 9, 2003 ART UNIT: 1614  
FOR: METHODS OF TREATING CANCER WITH HDAC INHIBITORS

**MAIL STOP IDS**

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

**TRANSMITTAL LETTER**

Transmitted herewith for filing in the present application are the following documents:

1. Information Disclosure Statement (2 pages), in duplicate;
2. Modified Form 1449/PTO (3 pages), in duplicate; and
3. Return Postcard.

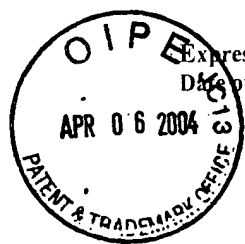
If the enclosed papers are considered incomplete, the Mail Room and/or the Application Branch is respectfully requested to contact the undersigned at (212) 935-3000.

The Commissioner is authorized to charge any fees that may be due to the undersigned's account, Deposit Account No. 50-0311 Ref. No. 24852-501 CIP2. Please address all correspondence to customer number **35437**. A duplicate copy of this transmittal letter is enclosed herewith.

Respectfully submitted,

Ivor Elrifi, Reg. No. 39,529  
Caryn DeHoratius, Reg. No. 45,881  
Attorney/Agent for Applicant  
c/o MINTZ, LEVIN, COHN, FERRIS  
GLOVSKY & POPEO P.C.  
The Chrysler Center  
666 Third Avenue  
New York, New York 10017  
Phone: (212) 935-3000  
Fax: (212) 983-3115

Dated: April 6, 2004



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## INFORMATION DISCLOSURE STATEMENT

Pursuant to the duty of disclosure under 37 C.F.R. §§1.56, 1.97 and 1.98, Applicants hereby make of record the documents listed on the attached modified Form PTO-1449, as well as copies of the listed documents.

This Information Disclosure Statement is being filed before the mailing date of a first Office Action on the merits, for the above-identified application. Accordingly, no fee or certification is believed required.

It is respectfully requested that the Examiner consider completely the cited information, along with any other information, in reaching a determination concerning the patentability of the present claims, and signs the enclosed form PTO-1449 to evidence that the cited information has been fully considered by the Patent and Trademark Office during the examination of this application.

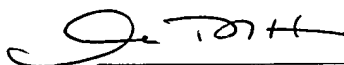
By submitting this Information Disclosure Statement, the Applicants make no representation that: (1) a search has been performed, of the extent of any search performed, or that more relevant information does not exist; (2) the information cited in the Statement is, or is considered to be, material to patentability as defined in 37 C.F.R. §1.56(b); and (3) the information cited in the Statement is, or is considered to be, in fact, prior art as defined by 35 U.S.C. §102.

Applicants: Chiao et al.  
U.S.S.N.: 10/616,649

The order of presentation of the references should not be construed as an indication of the importance of the references. The Examiner is urged to form his/her own conclusion regarding the relevance of the cited information.

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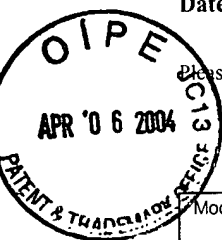
Respectfully submitted,



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Ivor R. Elrifi, Reg. No. 39,529  
Caryn DeHoratius, Reg. No. 45,881  
Attorney/Agent for Applicant  
c/o MINTZ, LEVIN, COHN, FERRIS  
GLOVSKY & POPEO P.C.  
The Chrysler Center  
666 Third Avenue  
New York, New York 10017  
Tel: (212) 935-3000  
Fax: (212) 983-3115

Dated: April 6, 2004



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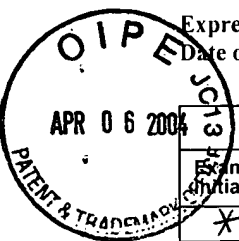
<b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>  (use as many sheets as necessary)	Application Number	10/616,649
	Filing Date	07/09/03
	First Named Inventor	Chiao
	Group Art Unit	1614
	Examiner Name	Not Yet Assigned
	Attorney Docket Number	24852-501 CIP2

U.S. PATENT DOCUMENTS							
Exam Initials	Cite No.	U.S. Patent Document No.	Issue Date	Name of Patentee(s) or Applicant(s)	Class	Sub Class	Filing Date
	A1*	5,055,608	10/08/91	Marks et al.	560	169	06/30/89
	A2*	5,175,191	12/29/92	Marks et al.	514	575	05/14/90
	A3*	5,369,108	11/29/94	Breslow et al.	514	266	10/04/91
	A4*	5,608,108	03/04/97	Marks et al.	562	621	04/17/95
	A5*	5,700,811	12/23/97	Breslow et al.	514	314	05/19/94
	A6*	5,773,474	06/30/98	Breslow et al.	514	616	06/07/95
	A7*	5,932,616	08/13/99	Breslow et al.	514	532	04/04/94
	A8*	6,087,367	06/11/00	Breslow et al.	514	266	05/18/99
	A9*	6,511,990	01/28/03	Breslow et al.	514	314	08/24/00

FOREIGN PATENT DOCUMENTS							
Exam Initials	Cite No.	Foreign Patent Document Office Number	Name of Patentee(s) or Applicant(s)		Date of Publication	Translation Yes No	
X	B1*	WO 98/40080	Beacon Laboratories, L.L.C.		September 17, 1998	X	
	B2*	WO 00/21979	Fujisawa Pharmaceutical Co., LTD		April 20, 2000	X	
	B3*	WO 00/71703	Methylgene, Inc.		November 30, 2000	X	
	B4*	WO 01/18171	Sloan-Kettering Institute for Cancer Research & The Trustees of Columbia University in the City of New York		March 15, 2001	X	
	B5*	WO 01/38322	Methylgene, Inc.		May 31, 2001	X	
	B6*	WO 01/70675	Methylgene, Inc.		September 27, 2001	X	
	B7*	WO 02/22577	Novartis-Erfindungen Verwaltungsgesellschaft M.B.H.		March 21, 2002	X	
	B8*	WO 02/30879	Prolifix Limited		April 18, 2002	X	
	B9*	WO 02/46144	F. Hoffmann-La Roche AG		June 13, 2002	X	

OTHER PRIOR ART - NON PATENT LITERATURE DOCUMENTS		
Exam Initials	Cite No.	Name of Author, Title (when appropriate), Publication, Volume, Page(s), Date, Etc.
X	C1*	Andrews et al. (2000). <i>Intl. J. Parasitol.</i> 30: 761-768.
	C2*	Archer et al. (1998). <i>Proc. Natl. Acad. Sci. USA</i> 95: 6791-6796.
	C3*	Bhalla et al. (2002). "Co-treatment With The Histone Deacetylase Inhibitor Suberoylanilide Hydroxamic Acid (SAHA) Enhances the Cytotoxic Effects of Gleevec and Arsenic Trioxide (AT) Against Bcr-Abl Positive Human Leukemia Cells." <i>American Society of Hematology</i> , 44 <sup>th</sup> Meeting of the American Society of Hematology, Abstract 4611.
	C4*	Butler et al. (2000). <i>Cancer Res.</i> 60: 5165-5170.
	C5*	Butler et al. (2001). <i>Clinical Cancer Res.</i> 7: 962-970.
	C6*	Butler et al. (2002). <i>Proc. Natl. Acad. Sci. USA</i> 99: 11700-11705.
	C7*	Coffey et al. (2000). <i>Medical and Pediatric Oncology</i> 35: 577-581.

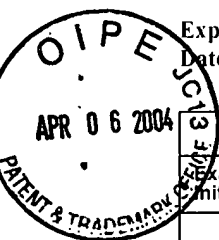
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OTHER PRIOR ART – NON PATENT LITERATURE DOCUMENTS

Exam Initials	Cite No.	Name of Author, Title (when appropriate), Publication, Volume, Page(s), Date, Etc.
*	C8*	Coffey et al. (2001). <i>Cancer Res.</i> <u>61</u> : 3591-3594.
	C9*	Cohen et al. (1999). <i>Anticancer Res.</i> <u>19</u> : 4999-5006.
	C10*	Cohen et al. (2002). <i>Anticancer Res.</i> <u>22</u> : 1497-1504.
	C11*	Curtin (2002). <i>Exp. Opin. Ther. Patents</i> <u>12</u> : 1375-1384.
	C12*	Dressel (2000). <i>Anticancer Res.</i> <u>20</u> : 1017-1022.
	C13*	Fei et al. (2002). "Co-treatment With the Histone Deacetylase Inhibitor Suberoylanilide Hydroxamic Acid (SAHA) Enhances Apo-2L/TRAIL-induced Death Inducing Signaling Complex and Apoptosis of Human Acute Lymphoid Leukemia Cells." <i>American Society of Hematology</i> , 44 <sup>th</sup> Meeting of the American Society of Hematology Abstract No. <b>4602</b> .
	C14*	Feinman et al. (2002). "The Histone Deacetylase Inhibitor, Suberoylanilide Hydroxamic Acid, Induces Apoptosis of Multiple Myeloma Cells." <i>American Society of Hematology</i> , 44 <sup>th</sup> Meeting of the American Society of Hematology, Abstract No. <b>3195</b> .
	C15*	Finnin et al. (1999). <i>Nature</i> <u>401</u> : 188-193.
	C16*	Furamai et al. (2001). <i>Proc. Natl. Sci. USA</i> <u>98</u> : 87-92.
	C17*	Grunstein (1997). <i>Nature</i> <u>389</u> : 349-352.
	C18*	He et al. (2001). <i>J. Clin. Investigation</i> <u>108</u> : 1321-1330.
	C19*	Hockly et al. (2003). <i>Proc. Natl. Acad. Sci. USA</i> <u>100</u> : 2041-2046.
	C20*	Kelly et al. (2001). "Suberoylanilide Hydroxamic Acid (SAHA), a Histone Deacetylase Inhibitor: Biologic Activity Without Toxicity." <i>American Society of Clinical Oncology</i> , Abstract No. <b>344</b> .
✓	C21*	Kelly et al. (2002). "Histone deacetylase inhibitor, suberoylanilide hydroxamic acid (SAHA), orally administered has good bioavailability and biologic activity." <i>American Society of Clinical Oncology</i> , 38 <sup>th</sup> Annual Meeting of the American Society of Clinical Oncology, November 7-10, 2002, Abstract No. <b>1831</b> .
	C22*	Kelly et al. (2002). "A phase I clinical trial of an oral formulation of the histone deacetylase inhibitor suberoylanilide hydroxamic acid (SAHA)." <i>European J. Cancer</i> <u>38</u> (Suppl. 7): 88, Abstract No. <b>286</b> .
	C23*	Kim et al. (1999). <i>Oncogene</i> <u>18</u> : 2461-2470.
	C24*	Kohge et al. (1998). <i>Biochem. Pharmacol.</i> <u>56</u> : 1359-1364.
	C25*	Komatsu et al. (2001). <i>Cancer Res.</i> <u>61</u> : 4459-4466.
	C26*	Kouraklis and Theocharis (2002). <i>Curr. Med. Chem. Anti-Cancer Agents</i> <u>2</u> : 477-484.
	C27*	Lee et al. (2001). <i>Cancer Res.</i> <u>61</u> : 931-934.
	C28*	Lin et al. (1998). <i>Nature</i> <u>391</u> : 811-814.
	C29*	Mai et al. (2001). <i>OPPI Briefs</i> <u>33</u> : 391-394
	C30*	Marks et al. (2000). <i>J. of the Natl. Cancer Institute</i> <u>92</u> : 1210-1215.
	C31*	Marks et al. (2001). <i>Clinical Cancer Res.</i> <u>7</u> : 759-760.
	C32*	Marks et al. (2001). <i>Curr. Opin. In Oncology</i> <u>13</u> : 477-483.
	C33*	Marks et al. (2001). <i>Nature Reviews</i> <u>1</u> : 194-202.
	C34*	Miller et al. (2003). <i>J Med Chem.</i> <u>46</u> : 5097-5116.
	C35*	Munster et al. (2001). <i>Cancer Res.</i> <u>61</u> : 8492-8497.
	C36*	O'Connor et al. (2002). "Clinical experience of the histone deacetylase inhibitor suberoylanilide hydroxamic acid (SAHA) in heavily pre-treated patients with aggressive non-hodgkin's lymphoma (NHL) and hodgkin's disease (HD)." <i>American Society of Clinical Oncology</i> , December 6-10, 2002, Abstract No. <b>4742</b> .
	C37*	Qui et al. (2000). <i>Mol. Biol. Cell</i> <u>11</u> : 2069-2083.
	C38*	Richon et al. (1996). <i>Proc. Natl. Acad. Sci. USA</i> <u>93</u> : 5705-5708.
	C39*	Richon et al. (1998). <i>Proc. Natl. Acad. Sci. USA</i> <u>95</u> : 3003-3007.
	C40*	Richon et al. (2000). <i>Proc. Natl. Acad. Sci. USA</i> <u>97</u> : 10014-10019.
	C41*	Richon and O'Brien (2002). <i>Clinical Cancer Res.</i> <u>8</u> : 662-664.
	C42*	Saito et al. (1999). <i>Proc. Natl. Acad. Sci. USA</i> <u>96</u> : 4592-4597.
X	C43*	Sgouros et al. (2002). "Synergistic Interaction of Suberoylanilide Hydroxamic Acid (SAHA) and

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Date of Deposit: April 6, 2004

## OTHER PRIOR ART – NON PATENT LITERATURE DOCUMENTS

Examiner Initials	Cite No.	Name of Author, Title (when appropriate), Publication, Volume, Page(s), Date, Etc.
		Radiation in Human Prostate Tumor Spheroids." <i>American Society of Clinical Oncology</i> , Abstract No. 105.
*	C44*	Stowell et al. (1995). <i>J. Med. Chem.</i> <u>38</u> : 1411-1413.
	C45*	Su et al. (2000). <i>Cancer Res.</i> <u>60</u> : 3137-3142.
	C46*	Suzuki et al. (1999). <i>J. Med. Chem.</i> <u>42</u> : 3001-3003.
	C47*	Van Lint et al. (1996). <i>Gene Expression</i> <u>5</u> : 245-253.
	C48*	Vrana et al. (1999). <i>Oncogene</i> <u>18</u> : 7016-7025.
	C49*	Webb et al. (1999). <i>J. Biol. Chem.</i> <u>274</u> : 14280-14287.
	C50*	Yoshida et al. (1990). <i>J. Biol. Chem.</i> <u>265</u> : 17174-17179.
	C51*	Yoshida et al. (1995). <i>BioEssays</i> <u>17</u> : 423-430.
	C52*	Zhou et al. (1999). <i>Gene</i> <u>233</u> : 13-19.
	C53*	Zhou et al. (2000). <i>Proc. Natl. Acad. Sci. USA</i> <u>97</u> : 1056-1061.
	C54*	Zhou et al. (2000). <i>Proc. Natl. Acad. Sci. USA</i> <u>97</u> : 14329-14333.
	C55*	Zhou et al. (2001). <i>Proc. Natl. Acad. Sci. USA</i> <u>98</u> : 10572-10577.

\*a copy of this reference is not provided as it was previously cited by or submitted to the office in a prior application, Serial No. **10/379,149**, filed **March 4, 2003**, and relied upon for an earlier filing date under 35 U.S.C. §120 (continuation, continuation-in-part, and divisional applications).

Examiner Signature		Date Considered	
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